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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/923,132	08/06/2001	Gary S. Sayler	6704-15-1	8944
7590	04/16/2004		EXAMINER	
BARBARA S. KITCHELL AKERMAN, SENTERFITT & EIDSON, P.A. 222 Lakeview Avenue, Fourth Floor P.O. Box 3188 West Palm Beach, FL 33402-3188			LAMBERTSON, DAVID A	
			ART UNIT	PAPER NUMBER
			1636	
DATE MAILED: 04/16/2004				

Please find below and/or attached an Office communication concerning this application or proceeding.

S/

<b>Office Action Summary</b>	<b>Application No.</b>	<b>Applicant(s)</b>	
	09/923,132	SAYLER ET AL.	
<b>Examiner</b>		<b>Art Unit</b>	
David A. Lambertson		1636	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) Responsive to communication(s) filed on 29 February 2004.
- 2a) This action is **FINAL**.      2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) Claim(s) 1-5,8-13,15,16,18,19 and 23-28 is/are pending in the application.
- 4a) Of the above claim(s) 4 is/are withdrawn from consideration.
- 5) Claim(s) 1-3,5,8-12,19 and 23 is/are allowed.
- 6) Claim(s) 13,15 and 24-28 is/are rejected.
- 7) Claim(s) 16 and 18 is/are objected to.
- 8) Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on \_\_\_\_\_ is/are: a) accepted or b) objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a) All    b) Some \* c) None of:  
1. Certified copies of the priority documents have been received.  
2. Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

1) <input type="checkbox"/> Notice of References Cited (PTO-892)	4) <input checked="" type="checkbox"/> Interview Summary (PTO-413)
2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)	Paper No(s)/Mail Date. _____
3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____	5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)
	6) <input type="checkbox"/> Other: _____

**DETAILED ACTION**

Receipt is acknowledged of a reply to the previous Office Action, filed February 9, 2004.

Amendments were made to the claims.

Claims 1-5, 8-13, 15, 16, 18, 19 and 23-28 are pending in the instant application. Claim 4 is withdrawn from consideration as being drawn to a non-elected invention. Any rejection of record in the previous Office Action, mailed October 21, 2003, that is not addressed in this action has been withdrawn.

Because this Office Action only maintains rejections set forth in the previous Office Action and/or sets forth new rejections that are necessitated by amendment, this Office Action is made FINAL.

This application contains claim 4, drawn to an invention non-elected with traverse. A complete reply to the final rejection must include cancellation of nonelected claims or other appropriate action (37 CFR 1.144) See MPEP § 821.01.

*Interview Summary*

Attached to the Office Action is an interview summary for the interview conducted January 28, 2004 between the Office and Applicant's representative. This paragraph is to clarify some of the assertions set forth in Applicant's response. First, it is noted that the Office did not indicate that the claims would absolutely be allowed upon the amendments set forth by Applicant; the Office clearly indicated that a reconsideration of the combination of the Lommi reference with the teachings of Lyngberg and Simpson would be necessary, and further noted that the application would require a 102(e) search prior to the allowance of the claims.

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Additionally, it is noted that Applicant has not made all of the amendments set forth in the Interview as necessary to obviate the current rejection under 35 USC 103(a) of Lyngberg in view of Simpson. Thus, the Finality of this Office Action in no way contradicts what was discussed or established in the interview.

***Priority***

Applicant's perfection of the priority claim is entered as satisfactory.

**New Grounds of Rejection**

***Claim Rejections - 35 USC § 112***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 25-27 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. **This is a new rejection that is necessitated by amendment to the claims.**

Claim 25 recites the limitation "said at least one construct" in the fourth line of the claim. There is insufficient antecedent basis for this limitation in the claim. There is no indication in the claim that more than one construct is integrated into the chromosome of the bioreporter bacterium, or what the nature of the "potential multiple constructs" encompasses. Furthermore, there does not appear to be clear support for the integration of multiple constructs into a host cell to construct a bioreporter bacterium. Thus it is unclear if Applicant means to indicate "wherein said construct" in reference to the instant limitation, or if there is some additional agenda

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contemplated by the term said at least one construct." It would be remedial to indicate "wherein said construct" in place of said at least one construct."

Maintained Rejections

*Claim Rejections - 35 USC § 112*

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 24, 26 and 28 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

It is apparent that the specific strains AR1, AR2 and AR3 are required to practice the invention. As such, the specific strains must be obtainable by a repeatable method set forth in the specification, or otherwise readily available to the public. If they are not so obtainable or available, a deposit of the bacterial strains may satisfy the requirements of 35 U.S.C. 112, first paragraph. In the instant case, the process to generate the specific strains that is disclosed in the specification does not appear to be repeatable (in the sense that the specific strains AR1, AR2 and AR3 are necessarily generated), nor does it appear the specific strains are readily available to the public. **This rejection is maintained for the reasons set forth in the previous Office Action, and is applied to claim 24 as amended, and claim 28 as newly added.**

It is noted that the portion of the rejection pertaining to claim 9, previously rejected under the statute, has been withdrawn; this is a particular substrain of *P. fluorescens* that is used as a host strain, and apparently not a particular strain that was created in the instant application.

***Response to Arguments Concerning Claim Rejections - 35 USC § 112***

Applicant's arguments filed February 9, 2004 have been fully considered but they are not persuasive. Applicant provides the following grounds for traversal: Applicant asserts that the instant specification provides adequate guidance on how to make strains AR1, AR2 and AR3 on page 20-21, and how to test these strains for their activity on page 21.

Applicant's arguments are not deemed convincing for the following reasons. First, it appears that Applicant intends to point to pages 19-20 for the process for making the specific strains AR1, AR2 and AR3. On these pages, Applicant describes a method for transforming a bacterium with a transposome (a DNA fragment bound by a transposase), wherein the transposome integrates the DNA (which contains the bioreporter) into the chromosome of the host cell in accordance with the mechanism of a transposase. What this entails is the virtual random integration of the DNA into the chromosome of the host cell at various positions, where the integration event may cause the mutation of endogenous genes. For any given host cell, this integration will be in a different position, and possibly effect the activity of any one of the genes endogenously present in the host cell. Thus, each time the method is performed, a *different* resulting strain is obtained. As such, Applicant has not described a method of making the specific host strains AR1, AR2 and AR3, *per se*; what they have described is a method of making bacterial host strains with a particular bioreporter integrated into the chromosome.

However, this is not the limitation of the claims, which specifically states that AR1, AR2 or AR3 must be used, and not some approximation of said strains. It is not guaranteed that the specific strains AR1, AR2 and AR3 will ever be generated by this method, and it is entirely possible that hundreds of thousands of other strains will instead be generated. Thus, Applicant's claim that the method of making the *specific strains* is repeatable is inaccurate.

Upon considering the method used to make the specific strains AR1, AR2 and AR3, one of skill in the art would recognize that these particular strains would be absolutely necessary in order to practice the specific invention claimed in claims 24, 26 and 28. This is because the likelihood of obtaining those specific strains by the transposition method taught in the specification is highly unlikely. Rather, it is likely that strains AR4, AR5, etc, will be obtained. Furthermore, because there is no description in the specification of where the transposition event occurred in any of the AR1, AR2 or AR3 strains, even if the skilled artisan were to win the lottery and generate one of the given strains, they would never know that that exact strain had been reproduced. Because it is clear that the *specific strains* cannot be made in a routine fashion, a deposit of these strains is necessary in order to enable the claimed invention, and the rejection is maintained.

#### ***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 13 and 15 are rejected under 35 U.S.C. 103(a) as being unpatentable over Simpson (US 6,117, 643 as cited in the previous Office Action; see entire document) in view of Lyngberg (IDS reference C-13, as cited in the previous Office Action; see entire document) as set forth in the previous Office Action. **This rejection is maintained for the reasons set forth in the previous Office Action.**

***Response to Arguments Concerning Claim Rejections - 35 USC § 103***

Applicant's arguments filed February 9, 2004 have been fully considered but they are not persuasive. Applicant provides the following grounds of traversal: Applicant asserts that "neither Lyngberg nor Simpson teach or suggests a device or method with the claims 'support matrix comprising a filter strip'" (original emphasis)(see page 12, first paragraph of Applicant's remarks).

Applicant's arguments are not convincing because, although neither Lyngberg nor Simpson appears to teach or suggest the use of a filter strip on a device or in a method, it is noted that: (a) claims 13 and 15 are not directed to either a device or a method, but to a genetically modified bacterium; (b) neither claim contains any limitation remotely similar to the presence of a "filter strip." As such, Applicant is arguing the absence of teachings for limitations that are not present in the claims, and this cannot be grounds to overcome a proper rejection. Thus, the rejection is maintained for the reasons set forth in the previous Office Action.

***Allowable Subject Matter***

Claims 13, 15 and 24-28 are rejected.

Claims 1-3, 5, 8-12, 19 and 23 are allowed.

Claims 16 and 18 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

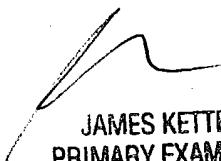
Any inquiry concerning this communication or earlier communications from the examiner should be directed to David A. Lambertson whose telephone number is (571) 272-0771. The examiner can normally be reached on 6:30am to 4pm, Mon.-Fri., first Friday off.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Remy Yucel, Ph.D. can be reached on (571) 272-0781. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

David A. Lambertson, Ph.D.  
AU 1636



JAMES KETTER  
PRIMARY EXAMINER